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EXAMINER

FOX, DAVID T

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/077,591
Filing Date: February 15, 2002
Appellant(s): LARKINS, JAMES

Robert E. Hanson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 14 May 2004.

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 3-4, 6, 11, 15-20 and 24-31.

Claims 1-2, 5, 7-10, 12-14 and 21-23 stand allowed.

(4) *Status of Amendments After Final*

No amendment after final has been filed.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 3-4, 6, 11, 15-20 and 24-31 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

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(8) Claims Appealed

A substantially correct copy of appealed claims 6, 11, 17, 22 and 31 appears on pages 31-34 of the Appendix to the appellant's brief. The minor errors are as follows:

In claims 6 and 11, line 2, "5" should be replaced with ---6---.

In claims 6 and 11, line 3, "6" should be replaced with ---7---.

In claim 17, line 1, the parenthesis before "A" should be deleted.

In claim 22, line 1, "F1" should be deleted.

In claim 31, the penultimate line, "addition" should be replaced with --additional--.

(9) Prior Art of Record

5,523,520

Hunsperger et al.

06-1996

Eshed et al. "Less-Than-Additive Epistatic Interactions of Quantitative Trait Loci in Tomato" Genetics, Vol. 143, (August 1996), pp. 1807-1817.

Kraft et al. "Linkage Disequilibrium and Fingerprinting in Sugar Beet" Theoretical and Applied Genetics, Vol. 101 (2000), pp. 323-326

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

35 USC 112, second paragraph

Claims 3-4, 6, 11, 15-20 and 27-30 on appeal stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention.

Claim 3 is indefinite in its recitation of "further defined as an essentially homogeneous population of seed" whose effect on the scope of the claim is unclear.

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The plain meaning of claim 2, on which claim 3 depends, is a homogeneous population of genetically identical inbred seed. Thus, the "essentially homogeneous" language would appear to be superfluous. However, reading the claims in light of the specification, lines 19-21 of page 5 indicate that inbred seed can form less than 100% of an essentially homogeneous population. Thus the scope of claim 3 is unclear. If claim 3 were amended to read ---An essentially homogeneous population of corn seeds consisting essentially of the inbred corn seed of claim 1---, the claim would have a definite meaning.

Claim 4 is indefinite in its recitation of "further defined as essentially free from hybrid seed" as its effect on the scope of the claim is unclear. Claim 2 from which it depends does not mention hybrid seed, and the plain meaning of that claim is a homogeneous population of inbred seed. Amending the claim to read ---A population of corn seeds consisting essentially of the inbred corn seed of claim 1, and essentially free from hybrid seed--- would obviate this rejection.

Appellant's Argument and Examiner's Response:

Appellant argues that while claim 2 is directed to a population of seed of corn variety I450436, it is not necessary that the population be essentially homogeneous. Appellant provides the definition for "population" from the Merriam-Webster on-line dictionary (Exhibit A), and argue that the relevant definition is "a body of persons or individuals having a quality or characteristic in common". Appellant also provides the definition for "homogeneous" (Exhibit B), which is "of uniform structure or composition throughout", and argues that a population of seed of corn variety I450436 could be non-

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uniform in size or shape, yet have the common quality of being a corn plant of variety I450436. Appellant argues that as such, claims 3-4 are in proper dependent form and are not indefinite. (Appeal Brief, page 6).

Appellant appears to be arguing that the recitation, "essentially homogeneous," in claim 3 indicates that the individual I450436 seed of the claimed population share a uniform structure, for example size and shape. However, the issue does not concern the size and shape of individual seeds. Further, Appellant's argument is inconsistent with the discussion of "essentially homogeneous population of inbred seed" in the specification. Page 5, lines 15-21, of the specification states, "Essentially homogeneous populations of inbred seed are those that consist essentially of the particular inbred seed, and are generally free from substantial numbers of other seed, so that the inbred seed forms between about 90% and about 100% of the total seed, and preferably, between about 95% and about 100% of the total seed. Most preferably, an essentially homogeneous population of inbred corn seed will contain between about 98.5%, 99%, 99.5% and about 99.9% of inbred seed, as measured by seed grow outs."

This definition does not concern the size and shape of the particular inbred seed of an essentially homogeneous population of inbred seed, but rather addresses the percentage of the population that is made up of the particular inbred seed versus other varieties of seed. The scope of claim 3 is unclear because the essentially homogeneous population of that claim can comprise varieties of seed other than I450436, whereas the population of claim 2 is directed to a single variety of seed, that of corn variety I450436. As noted above, amending claim 3 to read "An essentially

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homogeneous population of corn seeds consisting essentially of the seed of claim 1", would obviate this rejection. Suggested amendments to claim 4 have also been provided above.

Claims 6, 11 and dependents are indefinite in their recitation of "in accordance with" as the degree of identity intended is unclear. Furthermore, "an SSR profile...in Table 5" is unclear, as Table 5 depicts morphological trait characteristics of a single hybrid. Similarly, "an isozyme typing profile...in Table 6" is unclear, since Table 6 depicts SSR profiles, while Table 7 depicts isozyme profiles. Finally, "an...profile" is unclear, since each of Table 6 and Table 7 depict profiles from three inbred corn cultivars—the claimed cultivar and two others.

Appellant's Arguments and Examiner's Response:

Appellant provides the definition for "accordance" that appears in the on-line version of the Merriam-Webster Dictionary, one of which is "agreement, conformity" (Exhibit C). Appellant argues that the term therefore has a well known meaning in the art and its use in the claim is not indefinite (Appeal Brief, paragraph bridging pages 6 and 7).

It remains unclear whether the claimed inbred plant cell or plant has the SSR profile or the genetic isozyme typing profile of Tables 6 and 7. It is not clear, for example, what is meant by an SSR profile that is in conformity with the profile shown in Table 6. Is the SSR profile the same, or is it not the same, as that shown in Table 6? Would an SSR profile that generally follows the trend of the profile of Table 6, but which differs at one or a few loci, be considered in "conformity" or "in accordance" with the

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profile of Table 6? It is not clear what is meant by a marker profile that “agrees” with another marker profile. Are they the same or not? If the profiles are not exactly the same, then it is not clear what the differences are. If Appellant intends for the claimed inbred plant cell or plant to have the same profiles as those shown in Tables 6 and 7 for corn plant I450436, it is suggested that part (a) of claims 6 and 11 be replaced with --the SSR profile for corn plant I450436 shown in Table 6; or--, and that part (b) of the claims be replaced with --the isozyme typing profile for corn plant I450436 shown in Table 7--.

It is further noted that instant claims 6 and 11 have not been amended to correct the typographical errors concerning table numbers, as was done in copending appealed application Serial No. 10/077,589.

Claims 15, 17, 20 and dependents are indefinite in their recitation of “capable of”, as it is unclear whether or not the corn plant does or does not actually express the physiological and morphological characteristics of the exemplified corn inbred, at any developmental stage or in any environment. Claim 17 is also indefinite in its recitation of “capable of regenerating” as it is unclear whether or not the plants with the desired traits are actually regenerated. Replacement of “is capable of regenerating” and “capable of expressing” with ---regenerates--- and ---expressing---, respectively, would obviate this rejection.

Appellant’s Argument and Examiner’s Response:

Appellant argues that the term “capable” is well known in the art and is thus fully definite, and that claim breadth is not indefinite. Appellant argues that one of skill in the art “would understand whether a corn plant is capable of expressing all of the traits of

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corn plant I450436 by way of its biological deposit", and one would therefore "ascertain whether a plant is capable of expressing all of the traits of I450436 based on direct comparisons" (Appeal Brief, page 7, penultimate paragraph).

However, it is maintained that the recitation, "capable of expressing", renders the claim indefinite because the recitation can be interpreted to indicate that, while the plant has the capacity to express the characteristics, for some reason it may not. Certain characteristics of a plant are expressed only at certain times of its life cycle, and are incapable of being expressed at other times. The colors of flower parts such as silks, or fruit parts such as husks, are examples. The promoters of many genes conferring traits require a transcription factor to become active. Is a plant that has such a gene, but not the transcription factor, considered "capable of expressing" that gene, and the trait associated with that gene, and is such a plant encompassed by the claims?

Furthermore, traits such as plant height or yield are environmentally influenced. A particular value for plant height or seed yield observed in Appellant's tested growing environment might not be observed in another environment. The claim amendments suggested above particularly point out that the plant does have all of the morphological and physiological characteristics of I450436, while not requiring all of the characteristics to be expressed at all times of the plant's life cycle.

Claim 16 is indefinite in its recitation of "further comprising a nuclear or cytoplasmic gene conferring male sterility". The recitation appears to broaden the scope of its parent claim, or to raise some doubt as to whether the corn plant of claim 16 must be male sterile. The specification does not define plants expressing all the

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physiological and morphological characteristics of I450436 as being male sterile, or as comprising a gene that confers male sterility; in fact, the plant of claim 15 (from which claim 16 depends) is male fertile. Thus claim 16 cannot incorporate all the limitations of claim 15 because it is directed to a plant that is not male fertile. It is suggested that the claim be amended to recite that the plant was produced from the plant of claim 15 and to indicate how the gene conferring male sterility was introduced into the plant of claim 16.

Appellant's Argument and Examiner's Response:

Appellant argues that the claim is a proper dependent claim that specifies an additional characteristic, specifically, "a gene conferring male sterility", which is not in the independent claim. Appellant argues that claim 16 therefore contains a reference to the parent claim, contains a further limitation of the subject matter claimed in the main claim, and incorporates all elements of the claim from which it depends, and is therefore in proper dependent form pursuant to 37 CFR 1.75(c) (Appeal Brief, paragraph bridging pages 7 and 8).

However, claim 16 does not incorporate all elements of the parent claim. The plant of parent claim 15, which has all the physiological and morphological characteristics of I450436, is male fertile. See page 28 of the specification, fifteenth row of Table 3, where I450436 is characterized as having green-yellow anthers, wherein anther color is conferred by the presence of pollen. See also pages 24-25 of the specification, Tables 1 and 2, where I450436 is characterized as having pollen shed (see sixth row of each table). The plant of claim 16, however, is not male fertile.

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Therefore, claim 16 does not incorporate all elements of the claim from which it depends. Further, as the plant of claim 15 is male fertile, it is contradictory to say that claim 16 incorporates all elements of claim 15, yet is directed to a plant that is not male fertile.

The following amendments are suggested: introduce a new claim 32 that reads, --A method of producing a male sterile corn plant comprising transforming the plant of claim 15 with a nucleic acid molecule that confers male sterility.--, and a new claim 33 that reads, --A male sterile corn plant produced by the method of claim 32.--

Claims 27-30 are indefinite in the recitation in claim 27 of "corn plant of claim 5... comprising a single locus conversion"; and in the recitation in claim 28 of "wherein the single locus was stably inserted into a corn genome by transformation". These recitations appear to broaden the scope of claim 5, or raise some doubt as to whether the plants have all of the traits expressed by the plant of claim 5. Since claim 5 is drawn to a plant with defined characteristics and genotypes which exclude the presence of introduced single locus conversions or transgenes, it is confusing to simultaneously characterize these plants as comprising additional genes. Dependent claims 28-30 fail to remedy the deficiency of claim 27.

Appellant's Arguments and Examiner's Response:

Appellant argues that the recited limitation is in addition to that of the main independent claim. Appellant argues that the single locus conversion or transgene is added to and modifies the plant recited in the independent claim, that claim 27 contains a reference to the parent claim, contains a further limitation of the subject matter

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claimed in the main claim, and incorporates all elements of the claim from which it depends (Appeal Brief, paragraph bridging pages 7 and 8).

However, claim 27 adds an additional gene, and possibly an additional trait expressed by that gene, to the plant of claim 5. Claim 28 adds an additional transgene, and possibly an additional trait expressed by that transgene, to the plant of claim 5. For example, the single locus conversion or transgene may confer increased resistance against insects. The plant of claim 5 may be susceptible to insect damage, while the plants of claims 27 or claim 28, because of the additional single locus conversion or transgene, would be resistant to insects. Alternatively, the single locus conversion or transgene may confer the trait of male sterility on the plant, whereas inbred corn plant I450436 is male fertile, as discussed above. Thus, it is unclear if the plants of claims 27 or 28 have all of the traits possessed by the plant of claim 5.

Claim 28 is further indefinite in its recitation of "single locus was stably inserted into a corn genome" which is confusing, as a locus is a position on a genome rather than a piece of DNA or a gene. Furthermore, it is unclear whether the locus was inserted into the genome of the corn plant of claim 27, or some other corn plant, given the recitation of "a genome". Replacement of "a" with ---the--- would obviate this aspect of the rejection.

Appellant's Arguments and Examiner's Response:

Appellant notes that the single locus "may or may not have been directly inserted into the genome of the claimed plant", but argue that this does not render the claim indefinite, because the "single locus may have been inserted into a parent I450436 plant

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and self pollinated to produce the claimed plant". Appellant argues that the single locus need not have been directly inserted into the genome of I450436, and that loci that are stably inserted into a corn genome are also stably inherited (Appeal Brief, page 8, second full paragraph).

However, a parent plant of inbred variety I450436 is itself I450436. Therefore it remains unclear, what other genomes are encompassed by "a corn genome", and how does it relate to the plant of claim 28? Further, if the single locus is transformed into an entirely unrelated plant and introduced into I450436 by crossing and selection, the resultant plant would have the single locus but it would not otherwise be exactly the same as I450436.

Claim 29 is indefinite in its recitation of "locus is selected... dominant allele and a recessive allele" which is confusing, since a locus is a location on a genome, and is not an allele.

Appellant's Arguments and Examiner's Response

Appellant urges that the claim is not indefinite in view of Appellant's definition of "single locus conversion" in the specification, and the fact that the recitation of "locus" in claim 29 implies "single locus conversion" as recited in claim 27 (Appeal Brief, page 9, top three paragraphs). The Examiner disagrees that one skilled in the art would automatically interpret claim 29 as urged by Appellant. If claim 29 read, ---the conversion--- rather than "the locus", Appellant's arguments would be more persuasive. However, current claim 29 utilizes a definition of locus that is contrary to art-recognized usage of the term, and is thus indefinite. See MPEP 2173.03 and 2173.05(a).

Claim 30 is indefinite in its recitation of "yield enhancement", "improved nutritional quality", and "enhanced yield stability", as "enhanced" and "improved" are relative terms which do not clearly specify the degree of trait expression.

Appellant's Argument and Examiner's Response:

Appellant argues that those of skill in the art understand all the terms and "there is no prohibition upon the use of relative terms". Appellant argues that "the terms must be read in the context of the claim in which they are found"; that the "subject claim recites a single locus that confers the traits of yield enhancement, improved nutritional quality, and enhanced yield stability", and that it is understood that "the enhancement of yield or yield stability and improvement in nutritional quality is relative to a plant lacking the single locus". The metes and bounds of the claim would thus be fully understood by one of skill in the art (Appeal Brief, page 9, bottom paragraph).

However, relative terms cannot be used if the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Here, the specification does not provide any such standard. What one may consider an enhancement or improvement over a plant lacking the single locus, may not be considered so by another, in the absence of a defined standard that must be met. Further, what nutritional qualities are contemplated, and how are they improved?

35 USC 112, first paragraph, written description

Claims 16 and 24-31 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

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contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any corn plant produced by crossing inbred corn plant I450436 with any other uncharacterized corn plant of any genomic constitution over multiple unspecified generations for the introgression of any "single locus conversion" of any sequence and from any source organism which confers any trait (claims 27-29) or which confers particular traits (claims 16 and 30), wherein said introgression would result in the incorporation of uncharacterized non-I450436 genetic material besides the "single locus conversion" conferring the trait of interest; any hybrid corn seed produced by the process of crossing the inbred corn plant I450436 with any second, distinct, inbred corn plant, and any hybrid corn plant produced by growing said hybrid corn seed (claims 24-26); methods of repeatedly crossing I450436 with any other undefined non-I450436 parent over multiple generations (claim 31); any inbred corn plant produced by growing seed of inbred corn plant I450436, wherein said plant further comprises any transgene of any sequence and conferring any trait (claim 28); and any inbred corn plant which comprises any gene of any sequence which confers male sterility (claim 16).

The specification describes numerous morphological and physiological characteristics of inbred corn plant I450436 (pages 24-25 and 27-29, Tables 1-3). The response of 21 April 2003 indicates that a deposit of 2500 seeds of I450436 has been made with the American Type Culture Collection, in accordance with the requirements

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of 37 CFR 1.801-1.809 (see the page 3 of the response and pages 1-3 of the Kain declaration appended thereto). The specification also compares performance data for a single hybrid made by crossing I450436 with another different and genetically uncharacterized inbred (pages 54-59).

A review of the full content of the specification indicates that seed of inbred corn plant I450436, and hybrid seed produced by crossing a I450436 plant with any other corn plant, are essential to the operation and function of the claimed invention. A search of seed of inbred corn plant I450436 indicates that it is novel and unobvious.

A review of the language of claims 24-26 indicates that the claims are drawn to a genus, i.e., any and all hybrid corn seeds, and the hybrid corn plants produced by growing said hybrid seeds, wherein the hybrid seeds are produced by crossing inbred corn plant I450436 with any second, distinct inbred corn plant. Variation is expected in the complete genomes and phenotypes of the different hybrid species of the genus, since each hybrid has one non-I450436 parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles from the non-I450436 inbred parent. As a result, the complete genomic structure of each hybrid, and therefore the morphological and physiological characteristics expressed by each hybrid, would differ.

The specification does not describe any hybrid corn seeds or plants other than the single exemplified hybrid discussed above. There is no evidence on the record of a relationship between the structure of the complete genome of this hybrid and the complete genome of any other hybrid. There is no evidence on the record of any genetic composition or morphological characteristics of the other inbred used to make

the exemplified hybrid. The structure of the complete genome of the single non-I450436 inbred was not disclosed; nor was any relationship between the structure of its complete genome and the morphological characteristics of this inbred. Hybrids produced by crossing I450436 with other, distinct inbred corn plants would, of course, produce plants that do not express the same traits as I450436. Furthermore, hybrids produced by crossing I450436 with distinct inbred corn plants other than that used to produce the single exemplified hybrid also would not express the same I450436 traits as the single exemplified hybrid produced by crossing I450436 with the exemplified, albeit uncharacterized, non-I450436 inbred. The descriptions of I450436 and the single exemplified hybrid do not provide any information concerning the morphological and physiological characteristics of other plants. In view of these considerations, a person of skill in the art would not have viewed the teachings of the specification as sufficient to show that the Appellant was in possession of the claimed genus of hybrid seeds and plants produced therefrom.

The specification on page 30, top paragraph, also indicates that single locus converted plants (or "single gene converted plants") are defined as plants "which are developed by a plant breeding technique called backcrossing wherein *essentially all* [emphasis added] of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus or single gene transferred into the inbred via the backcrossing technique." The first step in the backcrossing process occurs when the exemplified inbred is outcrossed to a genetically distinct plant (the "donor plant" or "non-recurrent parent") which carries a

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gene or genes conferring a particular trait of interest, i.e. disease resistance. The donor plant may be a weedy relative of corn which contains many undesirable characteristics not suited for agriculture, such as low seed yield. Alternatively, the donor plant may be another commercially derived inbred which is suited to a different set of agronomic characteristics, i.e. adapted to grow in a different region of the country with different temperatures and different length of growing season. During classical breeding, unlike transformation or genetic engineering, a piece of DNA containing the actual gene conferring the desired trait is not isolated. Instead, a plant exhibiting that trait is identified, and then crossed to the plant of interest, wherein all of the additional genetic components of the donor plant are also transmitted to the progeny plant. Following this outcross to the donor plant, the resultant hybrid containing the desired gene is then repeatedly crossed back to the original inbred, the "recurrent parent", in an attempt to re-introduce the desired genes of the inbred into the progeny plant, and in an attempt to eradicate all of the other undesired genes present in the genome of the donor parent.

A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (or locus) on a plant chromosome. The specification contemplates numerous different single loci involved in expressing various traits (page 31, line 10 through page 35, line 9). However, the specification does not describe a multitude of non-exemplified transgenes conferring a multitude of unspecified traits, as claimed in claim 28, with regard to sequence, source, or function (i.e. conferred trait). Claim 28 reads on a multitude of transgenes of any

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sequence; from a multitude of unrelated sources such as viruses, bacteria, plants or animals; conferring a multitude of unrelated traits.

Furthermore, the specification provides no description of any plant produced by classical breeding methods such as backcrossing, as claimed in claims 16 and 27-31. No other corn plant ("donor parent") exhibiting a single desired trait for use in backcross breeding has actually been disclosed and described, and no resulting progeny from such a cross has actually been disclosed or described. Additionally, the remaining genetic complement of the donor parent, which comprises tens of thousands of other genes, in addition to the gene or genes responsible for the trait of interest, has not been characterized.

Furthermore, the individual genes conferring the desired traits (to be introgressed via classical breeding methods such as backcrossing) have not been characterized with respect to either sequence or source organism, and the genes for several of the contemplated traits; i.e. "improved nutritional quality", "yield enhancement" and "enhanced yield stability" as recited in claim 30, or "industrial usage" as recited on page 31 of the specification, line 15; have not been isolated either by Appellant or by the skilled artisan. In fact, the genes conferring such traits are thought to be quantitative in nature, i.e. governed by multiple genes, often occurring on different chromosomes, which additively contribute to the desired effect. Moreover, the single gene conversions of claims 27 and 29 were not characterized with respect to their function, since the claims do not recite a particular conferred trait conferred by the gene locus conversion, let alone the structure of the gene conversion (i.e. its sequence).

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Thus, claim 31 reads on a method for crossing I450436 with a multitude of non-exemplified breeding partners which have not been characterized either morphologically or genetically; and claims 16 and 27-30 read on the products of such a method. The progeny of such a method would contain varying amounts of non-I450436 genetic material contributed by the non-I450436 parent(s). This non-I450436 genetic material would alter the expression of the traits expressed by I450436. Only I450436 has been morphologically described in the specification, as possessing a particular combination of traits as set forth in pages 24-25 and 27-29 of the specification. I450436 has not been described with regard to its genetic complement, i.e. the particular collection of genes that confer all of the traits it exhibits. Furthermore, a plant with "essentially all" of the traits of I450436 has not been characterized. Even the exemplified single gene converted male sterile plant on pages 35-36 of the specification has not been characterized with respect to *any* of the I450436 traits listed in Tables 1-3 of the specification.

Moreover, other than the single hybrid produced by crossing I450436 once with a single other uncharacterized non-I450436 inbred, no progeny from the cross of I450436 with any other plant have been disclosed. Even this single hybrid was only described on the basis of a few traits as listed in Tables 4-5 on pages 57-59 of the specification. Furthermore, the non-I450436 inbred utilized in this cross was not described either morphologically or genetically.

The product of the method of claim 31, which would contain substantial amounts of non-I450436 genetic material, has not been characterized or described, because the

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collection of traits that it possesses has not been disclosed, and because it contains substantial amounts of non-I450436 genetic material which itself has not been described. To the extent that claim 31 reads on a backcrossing method, i.e. the "second plant" of steps (b) and (c) is I450436, wherein claims 16 and 27-30 would read on the products of a backcrossing method; the uncharacterized, non-I450436 genetic material present in the progeny would be minimized but not completely abolished, due to the maintenance of some non-I450436 genetic material in close proximity to the gene conferring the desired trait, which gene was obtained from the non-I450436 parent.

Alternatively, claim 31 may be interpreted to read on the repeated outcrossing of the progeny of part (a) with one or more completely uncharacterized non-I450436 plants; i.e. the "second plant" of steps (b) and (c) could be any other plant which is uncharacterized either genetically or morphologically; and each repetition of steps (b) and (c) up to 10 generations could include a completely different "second plant" than the one used in the prior repetition. Thus, claim 31 encompasses a method involving multiple crosses with multiple uncharacterized, non-I450436 parents, over multiple generations; wherein I450436 was only used once, in the initial outcross. Thus, even more uncharacterized non-I450436 genetic material would be present in the progeny of these plants, even if they were ultimately selfed in the last generation to produce an "inbred" as recited in the preamble, so that the products (i.e. progeny corn plants) of these methods would be even more uncharacterized with regard to genetic composition or morphological traits. The specification fails to disclose or describe any progeny resulting from such crosses, wherein said progeny could contain only a small portion of

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the I450436 genome, if any at all, and wherein said progeny would contain a majority of undisclosed and uncharacterized genetic material from a multitude of undisclosed and uncharacterized parents. Furthermore, no description has been provided for the progeny of such crosses with regard to even one morphological trait of said progeny containing a majority of non-I450436 genetic material.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus and structural features common to the genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Given the lack of written description in the specification regarding any of a multitude of non-I450436 parents to be used in a backcrossing breeding method or any other classical breeding method, one skilled in the art would not have recognized Appellant to have been in possession of the claimed hybrids, progeny plants or single locus conversion plants as recited in claims 16 and 24-30. Furthermore, given the lack of an adequate written description of the claimed progeny plants, any method of using said progeny plants in further crosses, as claimed in claim 31, would also be

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inadequately described. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

See also *University of Rochester v. G.D. Searle et al*, Appeal No. 03-1304, decided 13 February 2004 (Fed. Cir. 2004), at pages 14-15, which states that the written description requirement is not limited to cases involving isolated genetic sequences.

Furthermore, Claim 28 is drawn towards I450436 plants further comprising a foreign gene ("transgene") which was previously isolated as a piece of DNA, and then stably inserted into the corn genome by transformation. A review of claims 27-30 indicate that they encompass a genus of corn plants, each species of which can differ in the morphological and physiological traits that they can express, since they would comprise different transgenes or different single locus conversions. Claims 27-29 also do not place any limitation on the trait conferred or affected by the single locus conversion. The "single locus conversion" comprises an uncharacterized portion of DNA (locus) from a non-I450436 parent, which uncharacterized portion of DNA confers a particular trait. However, the specification does not describe identified or isolated single loci for all corn plant traits. The specification does not demonstrate the isolation of even one locus which could be used to convert I450436, and does not provide the sequence of any such locus, either in isolated form or as sequenced while still part of the rest of the non-I450436 nuclear genome. Claims 27-29 also broadly encompass single loci that have not been discovered or isolated.

All transgenes or single locus conversion that can be introduced into I450436 do not share the same structures (genetic sequences) and functions, and each transgene

or single locus conversion would have a different effect on the I450436 plant. No guidance has been provided which correlates the structure of all transgenes or single locus conversions with their function of conferring particular traits (claim 30) or of conferring unspecified traits (claims 27-29). See *University of California v. Eli Lilly* cited above.

The specification fails to provide an adequate written description of the genus of transgene or single locus conversion sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, or introgressing them into I450436 via classical breeding methods, and the resultant products including the claimed transformed plant cells and plants (or single gene converted plant cells and plants) containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed transgenic corn plants or methods of making or using them at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

See also MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Appellant's Arguments and Examiner's Response:

Appellant urges that the rejection of claim 16 as lacking an adequate written description is improper, given the availability of cytoplasmic and nuclear male sterility genes and their transfer into various corn genetic backgrounds (Brief of 14 May 2004, page 11, bottom paragraph; page 12, penultimate paragraph). The Examiner maintains that claim 16 as written is drawn to a corn plant which simultaneously is male sterile and male fertile, as discussed above in the rejection under 35 USC 112, second paragraph. One skilled in the art would not have recognized Appellant to have been in possession of such a plant at the time the invention was made.

Appellant urges that the specification describes a corn plant that "comprises essentially all of the desired morphological and physiological characteristics of corn plant I450436", that Appellant is not claiming undiscovered genes, and that Appellant is claiming a corn plant containing a single locus conversion or transgene, as opposed to claiming a single locus conversion or a transgene *per se* (Brief, page 10 through page 12, top paragraph).

Appellant has not described any transformed or single locus converted inbred plant which would retain all of the features of the exemplified inbred except for the introduced transgene-encoded or single locus conversion-encoded trait. It is unclear how the introduction of a multitude of non-exemplified transgenes, encoding a multitude of proteins or enzymes or inhibitory RNA products which would be involved in a multitude of metabolic pathways resulting in a multitude of traits, would interfere with one or more of these traits. Such interference would result in the production of a

multitude of corn plants with a different collection of traits than the exemplified inbred. Since no genetic characterization of the inbred was initially provided, and since the only identifying description of the inbred, namely the unique *collection* of traits, has now been obliterated, the genus of corn plants transformed with a multitude of non-exemplified transgenes would have been inadequately described. It is noted that claims limited to a method of producing a transgenic corn plant comprising transforming the exemplified inbred with single, known transgenes recited in the specification, and the resultant corn plant produced by that process, would in fact be adequately described, as stated previously.

In addition, Appellant has not described any plant which would exhibit “essentially all” of the characteristics of corn plant I450436. Appellant has only described the exemplified inbred with respect to a collection of traits, as set forth on pages 24-25 and 27-29. No guidance has been provided regarding how many of these traits must be retained, and how many may be lost, in order to constitute a plant exhibiting “essentially all” of the I450436 traits.

Furthermore, the Examiner maintains that Appellant’s specification explicitly recites genes conferring yield enhancement, nutritional enhancement, and industrial usage traits yet to be discovered, and that claim 30 explicitly claims them, as stated above. Accordingly, the genus of single locus conversions of claim 27, from which claim 30 depends, clearly encompasses these undiscovered genes, as well as innumerable others.

Regarding the claiming of plants containing genes, versus claiming genes *per se*, Appellant is directed to the Written Description Guidelines and to *University of Rochester v. G.D. Searle & Co., Inc.*, U.S. District Court, Western District of New York, Decision and Order No. 00-CV-6161L, decided 05 March 2003, at page 18, bottom paragraph, which support the Examiner's position that claimed products containing inadequately described genes are themselves inadequately described.

Regarding the description of transgenes or single locus conversions and corn plants containing them, Appellant argues that the Examiner supposedly ignored evidence submitted in a prior response that the specification recites numerous single locus traits with a publication reference or patent number. Appellant goes on to provide several examples (Appeal Brief, page 12, first full paragraph through page 14, first full paragraph). While the specification does cite references that describe numerous isolated genes, not all of the cited references actually teach that certain genes have been discovered or isolated. For example, the references cited in the specification do not describe isolated single genes or loci that confer yield enhancement, yield stability, enhanced nutritional quality, or industrial usage, as stated above. If such single loci have not been discovered or isolated, Appellant cannot be in possession of I450436 plants transformed with gene(s) conferring these traits. The claims broadly encompass plant I450436 further comprising any single locus conversion, controlling any trait, including loci that have yet to be identified as independently controlling a trait. Appellant cannot be in possession of plants further comprising single loci that have yet to be identified. In addition, Appellant has not provided any structural sequences common to

all of the transgenes or single locus conversions which were correlated with function, even for the putatively known transgenes and single gene conversions recited on pages 12 through 14 of the Brief.

It is also noted that the Examiner is not asking Appellant to identify each and every known or unknown gene by name, but merely to identify the types of single loci, that alone control a trait, that have been identified. For example, many genes or single loci were known in the prior art that confer disease resistance, herbicide resistance, and insect resistance; and the species of genes recited on pages 12-14 of the Brief mainly constitute these particular genera of genes. In the Office action mailed 30 January 2003, on pages 7-8, it was suggested that the claims be amended to recite these types of single gene loci, i.e. these particular types of genera, not individual or specific loci names. This suggestion was not adopted by Appellant.

Appellant argues that techniques for introducing single locus traits by genetic transformation were well known (Appeal Brief, paragraph bridging pages 14 and 15). That methods to produce genetically transformed corn plants existed at the time of the invention is, of course, not disputed. However, methods for producing a product do not reduce to practice the product itself. See *Bayer v. Housey*, Appeal No. 02-1598, (Fed. Cir. 2003), decided 22 August 2003, penultimate page: "processes of identification and generation of data are not steps in the manufacture of a final [drug] product".

In the Appeal Brief submitted 14 May 2004, Appellant again argues that the hybrid seeds and plants are described because they have I450436 as a parent and therefore contain a copy of the same genome as corn plant I450436, and that they have

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inherited half of their genetic material from I450436 (Appeal Brief, page 15, bottom paragraph).

First, the Examiner would like to address a statement made by Appellant that may be a point of confusion. Appellant states, "All of the claimed hybrid plants having I450436 as a parent will therefore contain a copy of the same genome as corn plant I450436" (emphasis added; Appeal Brief, page 15, bottom paragraph). By stating that the hybrids contain the same genome as I450436, this statement can be interpreted to mean that the entire genome of any of the claimed hybrids is identical to the entire genome of I450436. Since inbred corn plant I450436 must be crossed with a different corn plant to produce the claimed hybrids, the claimed hybrids cannot have entirely the same genome as I450436. It appears to the Examiner that Appellant did not intend to indicate that all of the claimed hybrid plants have entirely the same genome as I450436, as Appellant then immediately states, "That is, because I450436 is an inbred corn plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant I450436..." (emphasis added), which correctly indicates that all hybrids would inherit one-half, not all, of their genome from I450436.

The Examiner maintains that the claimed hybrids will not have the same morphological and physiological characteristics as I450436. I450436 can be crossed with any other inbred corn plant to produce the claimed hybrids. The claimed hybrids then will express a combination of morphological and physiological characteristics that are different from each other, and which are also different from those expressed by

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I450436. That all hybrids will inherit half of their alleles from I450436 does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids. The specification does not correlate any genes of I450436 with any of the traits that it expresses. Further, the claimed hybrids will inherit one allele for every gene from the other, unidentified and undescribed parent plant. The specification does not describe how those alleles inherited from I450436, or how the products of those alleles, will be affected by or interact with the alleles or their products inherited from the other parent. The expressed gene products will depend on the combination of the two alleles from each parent at each locus, whether the allele is dominant or recessive, and on the epistatic effects of other genes. The fact that any hybrid plant will inherit half of its alleles from I450436 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants.

For example, if I450436 carries two recessive alleles for insect resistance, it will be susceptible to insects. If it is crossed to another inbred with a recessive allele at that locus, the hybrid will also be susceptible to insects. If the other chosen inbred has a dominant allele at that locus, the hybrid will be insect resistant, if simple Mendelian genetics governs the inheritance of this trait. Each inbred possesses thousands of genetic loci governing thousands of traits, including silk color, lodging resistance, leaf color, stalk color, disease resistance, stalk stiffness, waxy starch, days to maturity, etc., with a dominant or recessive allele at each locus. It is clear that the mere provision of

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one-half of the hybrid's genetic complement being inherited from I450436 is woefully inadequate to describe the resultant hybrid, either genetically or morphologically.

Appellant also argues that the entire genetic contribution of corn plant I450436 is described by way of deposit of seed of I450436 with the ATCC, and believe that this represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishes them from other plants. In support of their argument, Appellant cites the decision of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, for holding that a biological deposit constitutes a written description of the deposited material (Appeal Brief, paragraph bridging pages 15 and 16; page 18, bottom paragraph through page 19, bottom paragraph).

However, in the patent considered in that decision, the deposited material corresponded exactly to one of the claimed products. The appeals court remanded the case for the district court to make findings on whether there was a correlation between the structure of the deposited material and the function of the variant material also claimed. Such a remand hardly indicates that the issue has been decided.

As in *Enzo*, here the deposited inbred does not correspond exactly to the claimed hybrid. However, the functions of the claimed hybrid plants have not been correlated to the half of their genetic material originating from the deposited I450436 seed. The function of the plant grown from a I450436 seed is correlated with the structure of its entire genome, not just one half. The function of the claimed hybrid plants grown from the claimed hybrid seeds is correlated with the structures of their entire genomes, not

just the alleles inherited from I450436. Further, half of the alleles of the hybrid are inherited from the other parent, and are not described by the deposited I450436 seed. Therefore, the claimed hybrids do not have the same, complete genetic structure and function as that possessed by the deposited I450436 seed, as discussed above.

Appellant continues, citing the decision of *The Regents of the University of California v. Eli Lilly and Co.*, for noting that "a name alone does not satisfy...written description" if "structural features commonly possessed by members of the genus" are not defined. Appellant argues that here, all of the members of the claimed genus of hybrids having I450436 as one parent share the identical feature of having the genetic complement of I450436 (Appeal Brief, page 16, first full paragraph). For the reasons explained above, the hybrids do not have the entire genetic complement of I450436, but only half that complement. In *Eli Lilly*, the members of the genus shared a common function. In the instant application, the specification does not describe the functions (i.e., morphological and physiological traits) of the claimed hybrids, and does not correlate the functions of the hybrids with the structure of the genetic complement of I450436. Furthermore, the genetic complement of the other unknown parent has not been described, and hence Appellant has not provided a written description of the multitude of possible hybrid corn plants that would result from crossing the deposited inbred I450436 with any and all other inbred or hybrid corn plants.

Appellant urges that the molecular marker data regarding SSR profiles on pages 59-61 and 63-65 demonstrate that any F1 hybrid will inherit the same genetic

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complement from inbred parent I450436. Thus, Appellant argues that the hybrid has been sufficiently described by virtue of its genetic marker profile (Brief, paragraph bridging pages 16 and 17; page 18, first full paragraph).

The Examiner maintains that the conservation of a set of molecular markers between a single hybrid and one of its inbred parents merely demonstrates that the inbred parent was indeed a parent of the hybrid. However, the set of molecular markers does not characterize the whole genome of the hybrid or the set of traits conferred by the hybrid genome, because the markers are not correlated with the particular set of traits exhibited by the hybrid. Indeed, the hybrid would exhibit many traits other than those exhibited by parent I450436, due to the presence of alternate, dominant alleles at a multitude of genetic loci of the second inbred parent. Thus, the conserved set of molecular markers is clearly not correlated with function, i.e. the conferring of a particular trait or set of traits to the resultant hybrid. Accordingly, the two-prong test of *University of California v. Eli Lilly*, namely the recitation of a representative number of species of the genus of all hybrids, and the correlation of structural features common to the genus of all hybrids, has not been met. Furthermore, the conserved set of markers fails to characterize that half of the hybrid genome which was inherited from the second, non-I450436 inbred parent.

Appellant continues, arguing that the second plant that is used to make the claimed hybrids is irrelevant, as any second plant capable of reproduction may be used to make the hybrid. Appellant argues that the claims cannot be said to lack written

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description for the second genetic complement, particularly given that “hundreds or even thousands of different inbred corn lines were well known to those of skill in the art”. Appellant points to the more than 300 patents issued for corn varieties as support, and argues that any one of these corn plants could be used to produce an F1 hybrid plant having I450436 as one parent, and each of these would share the genetic complement of I450436 (Appeal Brief, page 17, first full paragraph, through page 18, middle paragraph).

However, again, it is the interaction of the products of all of the alleles of the claimed hybrids, not just the products of the alleles inherited from I450436, which determine the traits of the claimed hybrids. Each parent contributes one set of chromosomes to the hybrid progeny, and each set of chromosomes comprises one allele for each gene at every locus in the genome, wherein alleles are alternate forms of the same gene that occur at a given locus. A phenotypic trait of the plant results from the expression of the two sets of alleles. The resulting phenotype of the plant depends on how each allelic product interacts with the corresponding allelic product inherited from the other genome, as well as how each gene product interacts with other gene products in the genome. Some alleles of the same gene are dominant to others. The interaction of nonallelic genes by epistasis also affects the phenotype, and quantitative traits are determined by the combined effects of multiple genes. Given that a claimed hybrid corn plant comprises a set of alleles inherited from each parent and these two sets of alleles interact in a variety of ways to determine the hybrid's morphological and physiological traits, one cannot correlate the alleles inherited from I450436 alone, with the phenotype of the hybrid progeny. Thus, the deposit of I450436 seeds and the recitation of some phenotypic characteristics of corn plant I450436 are not sufficient to

provide an adequate written description of all hybrid progeny that may be produced by crossing I450436 with a second, distinct corn plant. Appellant would have one believe that only half of a genome is sufficient to describe a plant. Yet, if only half of the genome of I450436 was deposited, it would not have been enough to describe its full genome, as discussed above.

Appellant next argues, in response to the Examiner's previous arguments that the morphological and physiological characteristics of the hybrids have not been described, and that the manner in which the genes inherited by the hybrids would be expressed or interact has not been shown; that the Examiner's position "misses the point that Appellants have gone one step further by describing the claimed hybrid plants at the genetic level." Appellants assert that "[a] better description could not be made than at the genetic level" (Appeal Brief, page 20, top paragraph).

However, again, Appellant is attempting to describe the claimed hybrids by only half of their genome. Appellant has deposited I450436 seed and, by extension, the I450436 genome, since the cells of the I450436 seed contain the I450436 genome. The claimed hybrids inherit only half of this genome, and the claimed hybrids do not have all of the same functions as those possessed by I450436. Given the genetic composition at each locus of the second inbred chosen as the hybrid's parent, the resultant hybrid may even have fewer than one-half of the traits exhibited by I450436.

Appellant repeats his argument that a further description of the claimed hybrid plants is provided in the specification by way of the single exemplified hybrid disclosed in Tables 4-5 of the specification, whose genetic marker profile is disclosed in Tables 8-

9 of the specification; and believes that this plant is representative of all hybrids produced using I450436 as one parent, each of which comprise the genetic complement of the parent corn plant (Appeal Brief, paragraph bridging pages 20 and 21). Appellant argues that this information "combined with the descriptions of I450436...and the shared structure among the hybrids...is more than adequate to describe the claimed subject matter".

However, again, hybrids that do not share both of the same parents will not have the same traits. The performance comparison of a single hybrid produced by crossing I450436 with a single other non-I450436 plants cannot be extended to any other hybrid plant that does not have both of the same parents; and is not representative of the genus of *all* hybrids produced using I450436 as only one parent, and using a multitude of genetically and morphologically uncharacterized and unrelated corn plants as a second parent. The presence in a genus of hybrids of even the same half of the genome, i.e. half of the genome of I450436, is completely non-predictive regarding the assortment of traits exhibited by the genus of such hybrids. At each of a multitude of genetic loci, conferring a multitude of traits including disease resistance, insect resistance, plant height, seed yield, cob color, anther color, lodging resistance, drought tolerance, etc., the allele from I450436 will interact with the allele from the non-I450436 parent. Depending upon the dominance of the allele from each parent, as well as epistatic interactions from other genes present in the non-I450436 parent's genome, each of a multitude of hybrids in the genus will exhibit a multitude of different collections of traits.

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Appellant urges that rejections of method claims as lacking an adequate written description are not in compliance with the Written Description Guidelines of 05 January 2001 (page 21 of the Brief, bottom paragraph, through page 23, bottom paragraph).

Appellant is directed to *University of Rochester v. G.D. Searle & Co., Inc.*, U.S. District Court, Western District of New York, Decision and Order No. 00-CV-6161L, decided 05 March 2003, at page 18, bottom paragraph, which teaches that method claims are properly subjected to a written description requirement if the starting material which requires that method is itself inadequately described. See also the rulemaking proceedings involved in creating the written description guidelines, 64 Fed. Reg. 71427, 71428, comment No. 4.

35 USC 112, first paragraph, enablement

Claims 16 and 24-31 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to corn plants containing a multitude of exemplified or non-exemplified single gene conversions or transgenes of any sequence and from any source organism, wherein said single gene conversions or transgenes confer a multitude of exemplified or non-exemplified traits, and wherein said single gene conversions were introduced into the corn plant via outcrossing with a multitude of non-exemplified corn plants containing the desired trait to be introduced (claims 16 and 27-

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30). The claims are broadly drawn towards any hybrid corn seed produced by the process of crossing the inbred corn plant I450436 with any second, distinct, inbred corn plant, and any hybrid corn plant produced by growing said hybrid corn seed (claims 24-26); and methods of repeatedly crossing I450436 with any other undefined non-I450436 parent over multiple generations (claim 30). Claim 16 also implies that the male sterile corn plant simultaneously contains all of the genetic and morphological characteristics of I450436, which is in fact male fertile, as discussed above.

No guidance has been provided for the isolation or characterization of a multitude of heterologous coding sequences ("transgenes") conferring a multitude of traits, as recited in claim 28. No guidance has been provided for identifying methods of using the resultant corn plants containing a multitude of unspecified transgenes conferring unspecified, if any, traits. Additionally, no guidance has been provided for *how to make* an I450436 corn plant which is simultaneously male fertile and male sterile, as claimed in claim 16.

In addition, no guidance has been provided for the introduction of any single desired trait (conferred by any "single locus conversion" DNA fragment) from a multitude of non-disclosed and uncharacterized donor breeding partners into I450436, as claimed in claims 16 and 27-30, by backcrossing or other means as claimed in claim 31, wherein the introduction of the desired trait should result in successful expression of the desired trait but should not interfere with the expression of the remaining I450436 traits. Furthermore, no guidance has been provided for preventing the introduction of unwanted genetic material conferring undesirable agronomic traits from the donor

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breeding partner into I450436. No guidance has been provided regarding the morphological or genetic composition of a multitude of non-exemplified breeding partners for crossing with I450436, either in a single cross to produce a hybrid corn plant as claimed in claims 24-26, or in multiple crosses with non-I450436 parents over multiple generations, as explicitly or implicitly claimed in claims 16 and 27-31. Given the lack of guidance regarding the genetic composition or morphological traits of the non-disclosed breeding partners, no guidance has been provided for methods of using the resultant progeny plants with unknowable morphological and genetic characteristics.

As discussed above, traditional plant breeding involves the crossing of two parents which contribute half of their entire genetic composition in an uncontrolled, random manner. A cross between I450436 and a non-I450436 parent, such as a weedy corn relative which possesses a gene for insect resistance, will result in a variety of progeny plants, each containing a different combination of half of the (thousands of) genes from each parent. Many of the traits found in I450436 will not be expressed by such progeny, and such progeny will express many traits conferred by the genes from the non-I450436 parent. If the non-I450436 parent is another agronomically desirable breeding line, the resultant progeny may contain a collection of traits which might be useful in some growing environments, such as early or late flowering, but not in the growing environment for which I450436 was intended. If the non-I450436 parent is a weedy relative of corn, the resultant progeny may contain many traits which are agronomically undesirable in any environment, such as low seed yield, small kernel size, small cob size, high susceptibility to stalk breakage, etc.

Following the initial production of progeny, plant breeders select those progeny which exhibit more desirable traits and fewer undesirable traits, and perform more crosses with these progeny, in the hopes that the genes conferring the desirable traits will be retained and transmitted to future generations, while the genes conferring the undesirable traits will be lost and not transmitted to future generations. The process of gene transmission following pollination is random, and the selection for desired traits results in the transmission of entire chromosomes containing many unknown or undesirable genes which are in close proximity to (or "linked" to) genes conferring desirable traits. Successful production of a classically bred variety depends upon the success of the selection for the desirable trait in each generation, the ability of the gene(s) conferring the desired trait to be expressed when it interacts with a variety of other non-exemplified genes in other genetic backgrounds, and the ability to select against undesirable traits conferred by genes which are linked to the genes conferring the desirable trait.

It is the *combination* of traits listed on pages 24-25 and 27-29 of the specification, rather than any *individual* trait or its expression, which confers patentability to I450436, and for which Appellant has taught a use. These traits include 1380-1416 growing degree units required from emergence to 50% of plants in flower (a measure of flowering time and subsequent corn kernel development in a particular climate with a particular length of pre-frost growing season), average plant height of 78.5 inches (which may be adapted for growing areas with high or low wind conditions), light leaf sheath pubescence (where relatively hairless leaves might confer an advantage in

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humid growing environments prone to fungal disease, but which would confer a disadvantage in dry environments because more water vapor would evaporate from the leaf surface), intermediate husk opening (where tight husks, which protect the kernels below, may be advantageous in growing environments with much wind or hail, but which would be disadvantageous to the consumer and so should be avoided when not needed), straight alignment of rows of kernels (which would be desirable for corn on the cob but unnecessary for corn to be removed from the cob for processing in canned or frozen form), roundness of kernels (which would affect their use as popcorn, corn on the cob, or processed canned or frozen corn), and normal endosperm starch (which would affect the kernels' use as sweet corn or as a source of corn syrup for sweetening processed food). These traits also include red cob, green-yellow pollen, and light green silks (female flowers), which combination of traits could be diagnostic for I450436.

It is not clear that single loci may be introduced into the genetic background of a plant through traditional breeding, while otherwise maintaining the genetic and morphological fidelity of the original inbred variety, even if followed by backcrossing to the original recipient parent I450436, as implicitly or explicitly claimed in claims 16 and 27-31.

Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired

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phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single locus conversion plant with a desired trait (column 3, lines 26-46). The gene conferring the desired trait may be properly expressed in some genetic backgrounds, but not expressed in other backgrounds, so that the trait would not be predictably conferred. Thus, a gene conferring disease resistance in one donor variety of corn may not function properly when transferred into I450436, due to the interactions with all of the other I450436 genes that were not present in the original donor variety.

Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single locus conversion but otherwise maintaining all of the desired genes and traits of the recipient parent, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Linkage drag refers to the close proximity on the chromosome of genes conferring undesirable traits to a gene conferring a desirable trait. Due to such close proximity, it is virtually impossible to remove the genes conferring the undesirable trait from progeny of crosses which were selected for the desirable trait. The situation becomes even more complex

when it involves traits such as seed yield which are affected by multiple genes on multiple chromosomes, i.e. "quantitatively inherited" traits.

Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). Epistasis refers to the unpredictable interaction of various genes with each other. Such epistasis may result in the inhibition of one gene by another, so that a gene conferring insect resistance, which functions in a particular donor plant, would not function in I450436 or a progeny thereof, due to the presence of other genes in I450436 or the progeny which inhibit the function of the insect resistance gene. In quantitative traits, which are governed by the combined action of many genes, each conferring a small effect on the trait, the situation is even more pronounced. In quantitative traits such as yield, high yield of 200 bushels per acre may be the result of the contribution of 20 genes on different chromosomes, each conferring an incremental yield increase of 10 bushels per acre, when acting in an additive fashion. Due to epistatic interactions with other genes in other genetic backgrounds, even if all 20 genes were present, they would not act additively to cause a yield of 200 bushels per acre. Perhaps half of the genes would be inhibited, giving a low yield of only 100 bushels per acre. Furthermore, some of the 20 genes might not even be transmitted to the progeny, due to random gene segregation as well as the selection against undesirable traits conferred by genes linked to some of the 20 high yield genes.

In the absence of further guidance, undue experimentation would have been required by one skilled in the art to overcome the difficulties and unpredictability of backcross conversions taught in the prior art, in order to yield the claimed plants which differ from I450436 only in comprising a single locus conversion and by the expression of a single trait. It appears that even backcrossing attempts, as implicitly claimed only in claim 31, would result in the production of plants with many undesirable traits which are conferred by genetic material linked to the gene conferring the trait of interest.

If backcrossing to I450436 were not attempted, as claimed in claims 16, 27-30, and as alternately claimed in claim 31 as discussed above, even more undesirable, non-I450436 genetic material would remain in the progeny plants, further obliterating the desirable collection of traits exhibited by I450436. Every time that I450436 is crossed to a non-I450436 parent, half of the genetic contribution of I450436 is lost. The resultant progeny of the process of claim 31, which involves an initial cross of I450436 with another plant, and which then involves up to ten additional crosses with non-I450436 plants, would have as little as $1/1024^{\text{th}}$ or 0.09765% of its genetic material derived from I450436, and the remaining 1023/1024 or 99.90235% of its genetic material would be comprised of undefined genetic material from the other non-I450436 parents involved in the crosses. No guidance has been provided regarding the use of said progeny, which contain less and less I450436 genetic material, and which therefore exhibit fewer and fewer I450436 traits.

Regarding the use of single locus conversions or transgenes, claims 27-29 do not specify the sequence of the single locus conversion or transgene; the source of the

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transgene which may be from bacteria, fungi, animals or plants; or the encoded product of the single locus conversion or transgene, such as a multitude of proteins or enzymes, or reverse-orientation RNA molecules which inhibit the expression of other genes, etc. These claims do not even specify the traits which result from the introduction and successful expression, if any, of the single locus conversion or transgene. (Note that the Examiner has previously suggested that claims should be submitted which at least specify the traits encoded by the genes, when such genes encoding such traits have already been isolated by other skilled artisans, such as herbicide resistance, disease resistance, insect resistance, waxy starch, etc.)

However, the specification does not enable transforming I450436 cells with all transgenes. Furthermore, the specification does not enable the introgression of a multitude of non-exemplified single locus conversions conferring a multitude of non-exemplified traits from a multitude of non-exemplified parents. As broadly interpreted, the claimed plants and method encompass introducing any type of single locus conversion or transgene into I450436, including those that have not been isolated or identified at the time the application was filed. The prior art shows that hundreds of nucleotide sequences encoding products that confer various types of plant traits have been isolated at the time the instant invention was filed. One skilled in the art can transform any of these isolated nucleotide sequences known in the prior art into a corn plant cell, and regenerate a transgenic plant from the transformed cell. However, the claims do not place any limit on the single locus conversions or transgenes to be introduced, and encompass transgenes for plant traits that have yet to be isolated. For

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example, isolated genes whose products confer yield enhancement, enhanced yield stability, improved nutritional content, or industrial usage, are not known in the prior art. One skilled in the art cannot practice the claimed method and produce the claimed plants if the nucleotide sequence whose product confers a desired trait has not been isolated at the time the instant invention was made.

See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). Also, transgene or single locus conversion DNA, as broadly interpreted, includes isolated genes whose functions are not known. If the effect of expressing a transgene or single locus conversion in I450436 were not known, one skilled in the art would not know *how to use* the transformed plant. See also Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Further, the effects of transgene or single locus conversion expression on the traits expressed by untransformed or unconverted I450436 are unknown. The specification does not teach one how to use a transformed or converted I450436 plant if all of the morphological and physiological traits of I450436 are not expressed. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would have been required by one skilled in the art to make and use the claimed invention.

Appellant's Arguments and Examiner's Response:

Appellant urges that the enablement rejection regarding single locus conversions is improper, given the disclosure in the specification of a single locus converted plant containing a male sterility gene (Brief, page 24, top paragraph). The Examiner maintains that Appellant has not disclosed the actual phenotype of the exemplified male sterile backcross conversion regarding *any* of the I450436 traits listed in Tables 1-3 of the specification. It is highly unlikely that the backcross conversion would possess all of the traits of I450436, as set forth above, and no guidance has been provided regarding which traits would be retained and which would not. Thus, no guidance has been provided by Appellant for *how to use* the single exemplified backcross conversion plant disclosed on pages 35-36 of the specification. Furthermore, no guidance has been provided for how to use a plant which is simultaneously male sterile and male fertile, as claimed in claim 16.

Appellant urges that the enablement rejection regarding the production of male-sterile plants is improper, given the decades-long availability of genes and breeding techniques just for this purpose (Appeal Brief, page 24, middle paragraph). The Examiner does not dispute this, but merely maintains that techniques for producing a plant which is simultaneously male fertile and male sterile are not available. Amending claim 16 to overcome the rejection under 35 USC 112, second paragraph, would obviate the rejection of this claim as lacking enablement.

Turning to the aspect of the rejection concerning the enablement of corn plants derived from variety I450436 and produced by classical breeding methods involving

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non-I450436 plants as breeding partners, including backcross breeding methods to produce I450436 plants comprising a single locus conversion, Appellant argues that, as noted before, no basis has been given to show that the references cited by the Examiner to support his position have any relevance to corn plants. Appellant urges that corn breeding is much more well-developed than the breeding of petunias, sugar beets or tomatoes. Appellant further urges that references that pertain to dicotyledonous, or broad-leaved, plants such as tomato, petunia and sugar beet are inapplicable to monocotyledonous, or narrow-leaved plants such as corn, per *Plant Genetic Systems v. Dekalb Genetics Corp.* Appellants argue that there is no support for the Examiner's assertion that the cited references concerning petunias, sugar beets, and tomatoes would apply to corn, and that the Action attempts to require Appellants to show why this is not true. Appellant argues that it is the burden of the Office to support its rejections (Appeal Brief, page 24, bottom paragraph through page 26, first full paragraph).

The rejection raises the issue of how linkage drag hampers the insertion of single genes alone into a plant by backcrossing, while recovering all of the original plant's genome. Linkage drag appears to be a phenomenon that occurs in all plant types, including the three unrelated species set forth in the references cited by the Examiner. Examples are lacking in the prior art of plants in which linkage drag does not occur. There is no evidence that corn is exempt from this universal trend. Linkage drag, for reasons embellished in the previous Office action and repeated above, would prevent one skilled in the art from making the I450436 plants comprising single locus

conversions as currently claimed in claims 16 and 27-30. Furthermore, linkage drag would result in the maintenance of numerous non-I450436 genes, conferring numerous agronomically undesirable traits, in any progeny produced by crossing I450436 only a single time, followed by continued generations of outcrossing to non-I450436 parents, as claimed in claim 31. The cited references demonstrate the *widespread* phenomenon of unpredictability, throughout cultivated plant species, in utilizing classical breeding by crossing two different plants in order to transfer desired traits while preventing the transfer of linked deleterious traits. The fact that these references are not specific to corn is immaterial. Appellant has not provided any evidence that this phenomenon does not occur in maize, and has not provided any guidance to overcome this unpredictability.

Regarding the issue of monocotyledonous versus dicotyledonous plants, the Examiner notes that the cited case law dealt with methods of plant transformation and plant cell tissue culture, wherein said methods had been historically more developed for dicots than for monocots, particularly at the time that the applications in question were filed. However, in the instant case, the Examiner relied upon references dealing with three different dicotyledonous plant species in order to demonstrate the unpredictability inherent in particular aspects of *classical plant breeding*, involving neither transformation nor tissue culture. Although corn breeding may be well-developed with regard to the acreage devoted to new corn varieties, the problems that plague other crops regarding the transfer of discrete genes conferring discrete traits, while otherwise

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retaining the virtually complete genetic fidelity of the original recipient parent, appear to be equally applicable in corn.

Appellant urges that claims 24-26 drawn to hybrids and methods of their use were improperly rejected as non-enabled, given Appellant's disclosure of a single hybrid produced with I450436 as one of its parents, and the availability of hundreds of corn varieties to be used as the second parent, wherein the choice of the non-I450436 parent would not in any way hamper the ability of this parent to be crossed with I450436 in order to produce a hybrid corn plant (Appeal Brief, page 26, second full paragraph, through page 27, top paragraph).

The Examiner maintains that the specification enables the single exemplified hybrid because it provides its morphological characteristics, as set forth in Tables 4-5 on pages 57-59 of the specification. Thus, the specification teaches *how to use* this hybrid, and a claim limited to this hybrid would be deemed enabled. However, as the claimed hybrid comprises only half of the genetic complement of I450436, and possesses a multitude of unknown traits from a multitude of non-exemplified parents whose genetic composition has also been uncharacterized, one skilled in the art would not know how to use such a hybrid plant with unspecified traits. Each of the hundreds of available corn inbreds have a multitude of genes conferring a multitude of traits which are useful in particular environments, as discussed above. In addition, one skilled in the art could not predict the genetic and morphological complement of any hybrid produced by crossing I450436 with a multitude of non-exemplified and uncharacterized second parents, as stated above, even if said second parents were indeed available. Thus, one

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skilled in the art would not know *how to use* the multitude of hybrids produced therefrom. Furthermore, if the second parent were a weedy corn relative or another type of non-agronomic corn variety, the resultant hybrid product would be even less useful.

Appellant urges that the enablement rejection over processes of using I450436 in other classical breeding methods is improper, given the enablement of I450436 itself and the knowledge of the claimed breeding methods by the artisan of ordinary skill (Appeal Brief, page 27, bottom paragraph).

The Examiner maintains that since the genetic or morphological complements of the second and subsequent breeding partners have not been identified, the genetic and morphological traits of the resultant products of those breeding processes are unknowable. Thus, one skilled in the art would not know *how to use* the products of such methods.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "David T. Fox".

David T. Fox
Primary Examiner
Art Unit 1638

December 17, 2004

Conferees

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